

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		10044031
	Filing Date		2002-01-11
	First Named Inventor	Badylak et al.	
	Art Unit	3774	
	Examiner Name	Paul B. Prebilio	
	Attorney Docket Number	3220-69262	

U.S.PATENTS						Remove
Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	2172903		1939-09-12	Charping	
	2	3346401		1967-10-10	Barat et al.	
	3	3632361		1972-01-04	Battista	
	4	3649163		1972-03-14	McCusker	
	5	4193813		1980-03-18	Chvapil	
	6	4292972		1981-10-06	Pawelchak et al.	
	7	4320201		1982-03-16	Berg et al.	
	8	4347234		1982-08-31	Wahlig et al.	

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number		10044031
Filing Date		2002-01-11
First Named Inventor	Badylak et al.	
Art Unit		3774
Examiner Name	Paul B. Prebilio	
Attorney Docket Number		3220-69262

	9	4394370		1983-07-19	Jefferies	
	10	4404970		1983-09-20	Sawyer	
	11	4409332		1983-10-11	Jefferies et al.	
	12	4412947		1983-11-01	Cioca	
	13	4421947		1983-12-20	Kyle	
	14	4472840		1984-09-25	Jefferies	
	15	4578067		1986-03-25	Cruz Jr	
	16	4606337		1986-08-19	Zimmermann et al.	
	17	4681588		1987-07-21	Ketharanathan	
	18	4755593		1988-07-05	Lauren	
	19	4798611		1989-01-17	Freeman, Jr.	

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number		10044031
Filing Date		2002-01-11
First Named Inventor	Badylak et al.	
Art Unit		3774
Examiner Name	Paul B. Prebilic	
Attorney Docket Number		3220-69262

	20	4801299		1989-01-31	Brendel et al.	
	21	4813958		1989-03-21	Dixon	
	22	4837379		1989-06-06	Weinberg	
	23	4838888		1989-06-13	Nashef	
	24	4885005		1989-12-05	Nashef et al.	
	25	4891359		1990-01-02	Saferstein et al.	
	26	4925924		1990-05-15	Silver et al.	
	27	4948540		1990-08-14	Nigam	
	28	4950483		1990-08-21	Ksander et al.	
	29	4969912		1990-11-13	Kelman et al.	
	30	4970298		1990-11-13	Silver et al.	

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number		10044031
Filing Date		2002-01-11
First Named Inventor	Badylak et al.	
Art Unit		3774
Examiner Name	Paul B. Prebilic	
Attorney Docket Number		3220-69262

	31	4976733		1990-12-11	Girardot	
	32	4994084		1991-02-19	Brennan	
	33	5024841		1991-06-18	Chu et al.	
	34	5071436		1991-12-10	Huc et al.	
	35	5094661		1992-03-10	Levy et al.	
	36	5106949		1992-04-21	Kemp et al.	
	37	5141747		1992-08-25	Scholz	
	38	5171574		1992-12-15	Kuberasampath et al.	
	39	5206023		1993-04-27	Hunziker	
	40	5206028		1993-04-27	Li	
	41	5215541		1993-06-01	Nashef et al.	

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number		10044031
Filing Date		2002-01-11
First Named Inventor	Badylak et al.	
Art Unit		3774
Examiner Name	Paul B. Prebilic	
Attorney Docket Number		3220-69262

	42	5219576		1993-06-15	Chu et al.	
	43	5256418		1993-10-26	Kemp	
	44	5279612		1994-01-18	Eberhardt	
	45	5298222		1994-03-29	O'Leary	
	46	5368608		1994-11-29	Levy et al.	
	47	5374515		1994-12-20	Parenteau et al.	
	48	5397352		1995-03-14	Burres	
	49	5411887		1995-05-02	Sjolander	
	50	5413791		1995-05-09	Rhee et al	
	51	5446462		1995-08-29	Cleveland	
	52	5447536		1995-09-05	Girardot et al.	

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number		10044031
Filing Date		2002-01-11
First Named Inventor	Badylak et al.	
Art Unit		3774
Examiner Name	Paul B. Prebilio	
Attorney Docket Number		3220-69262

	53	5451406		1995-09-19	Lawin et al.	
	54	5456693		1995-10-10	Conston et al.	
	55	5457093		1995-10-10	Cini et al.	
	56	5466462		1995-11-14	Rosenthal et al.	
	57	5476516		1995-12-19	Seifter et al.	
	58	5480427		1996-01-02	Kelman et al.	
	59	5489022		1996-02-06	Baker	
	60	5489261		1996-02-06	Franzblau et al.	
	61	5498420		1996-03-12	Mentrup Edgar et al.	
	62	5501706		1996-03-26	Arenberg	
	63	5510121		1996-04-23	Rhee et al.	

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number		10044031
Filing Date		2002-01-11
First Named Inventor	Badylak et al.	
Art Unit		3774
Examiner Name	Paul B. Prebilio	
Attorney Docket Number		3220-69262

	64	5510418		1996-04-23	Rhee et al.	
	65	5512291		1996-04-30	Li	
	66	5514181		1996-05-07	Light et al.	
	67	5516395		1996-05-14	Anhauser et al.	
	68	5520925		1996-05-28	Maser	
	69	5522840		1996-06-04	Krajicek	
	70	5531786		1996-07-02	Perry et al.	
	71	5531791		1996-07-02	Wolfinbarger, Jr.	
	72	5565210		1996-10-15	Rosenthal et al.	
	73	5567806		1996-10-22	Abdul-Malak et al.	
	74	5571181		1996-11-05	Li	

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number		10044031
Filing Date		2002-01-11
First Named Inventor	Badylak et al.	
Art Unit		3774
Examiner Name	Paul B. Prebilic	
Attorney Docket Number		3220-69262

	75	5607476		1997-03-04	Prewett et al.	
	76	5607590		1997-03-04	Shimizu	
	77	5693085		1997-12-02	Buirge et al.	
	78	5707962		1998-01-13	Chen et al.	
	79	6099567		2000-08-08	Badylak et al.	
	80	6475232		2002-11-05	Babbs et al.	
	81	6666892		2003-12-23	Hiles et al.	
	82	7029434		2006-04-18	Carpentier et al.	
	83	5731418		1998-03-24	Jain	
	84	5153067		1992-10-06	Yoshida (deceased) et al.	
	85	5891558		1999-04-06	Bell et al.	

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	10044031
Filing Date	2002-01-11
First Named Inventor	Badylak et al.
Art Unit	3774
Examiner Name	Paul B. Prebilio
Attorney Docket Number	3220-69262

86	3103283		1963-09-10	Preuss	
87	5261422		1993-11-16	Kelly	
88	6206931		2001-03-27	Cook et al.	
89	6666892		2003-12-23	Hiles et al.	
90	7652077		2010-01-26	Cook et al.	

If you wish to add additional U.S. Patent citation information please click the Add button.

Add

U.S.PATENT APPLICATION PUBLICATIONS

Remove

Examiner Initial*	Cite No	Publication Number	Kind Code ¹	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1	20020048595		2002-04-25	Geistlich et al.	
	2	20010048949		2001-12-06	Atala	
	3	20080213335		2008-09-04	Cook et al.	
	4	20080167727		2008-07-10	Cook et al.	

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	10044031
Filing Date	2002-01-11
First Named Inventor	Badylak et al.
Art Unit	3774
Examiner Name	Paul B. Prebilio
Attorney Docket Number	3220-69262

5	20080171092		2008-07-17	Cook et al.	
6	20080167728		2008-07-10	Cook et al.	
7	20040137042		2004-07-15	Hiles et al.	
8	20080063680		2008-03-13	Hiles et al.	
9	20080145397		2008-06-19	Hiles et al.	
10	20080145395		2008-06-19	Hiles et al.	

If you wish to add additional U.S. Published Application citation information please click the Add button. [Add](#)

FOREIGN PATENT DOCUMENTS

[Remove](#)

Examiner Initial*	Cite No	Foreign Document Number ³	Country Code ² i	Kind Code ⁴	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear	T ⁵
	1	WO 98/25545	WO		1998-06-18	Cook Biotech Inc.		<input type="checkbox"/>
	2	WO 96/31225	WO		1996-10-10	Purdue Research Foundation		<input type="checkbox"/>
	3	GB 2266239	GB		1993-10-27	Jevco Ltd.		<input type="checkbox"/>

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number		10044031
Filing Date		2002-01-11
First Named Inventor	Badylak et al.	
Art Unit		3774
Examiner Name	Paul B. Prebilio	
Attorney Docket Number		3220-69262

4	WO 00/32250	WO		2000-06-08	Cook Biotech Incorporated		<input type="checkbox"/>
5	WO 85/04413	WO		1985-10-10	Uni. of Med. & Dent. NJ		<input type="checkbox"/>
6	WO 95/22611	WO		1995-08-24	University of Michigan		<input type="checkbox"/>
7	WO 96/24661	WO		1996-08-15	Purdue Research Foundation		<input type="checkbox"/>
8	WO 96/32146	WO		1996-10-17	Advanced Cytometrix, Inc.		<input type="checkbox"/>
9	WO 98/22158	WO		1998-05-28	Cook Biotech et al.		<input type="checkbox"/>
10	WO 98/25636	WO		1998-06-18	Purdue Research Foundation		<input type="checkbox"/>
11	WO 98/25637	WO		1998-06-18	Purdue Research Foundation		<input type="checkbox"/>
12	WO 98/26291	WO		1998-06-18	Purdue Research Foundation		<input type="checkbox"/>
13	EP 0405429	EP		1991-01-02	Euroresearch S.R.L. et al.		<input type="checkbox"/>
14	EP 0925077	EP		1998-05-28	Cook Biotech Incorporated		<input type="checkbox"/>

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	10044031
Filing Date	2002-01-11
First Named Inventor	Badylak et al.
Art Unit	3774
Examiner Name	Paul B. Prebilit
Attorney Docket Number	3220-69262

15	WO 95/18529	WO		1995-07-13	Organogenesis, Inc.		<input type="checkbox"/>
16	WO 94/26175	WO		1994-11-24	Vitaphore Corporation		<input type="checkbox"/>
17	WO 97/19643	WO		1997-06-05	Endomatrix, Inc.		<input type="checkbox"/>
18	WO 99/44538	WO		1999-09-10	The Regents of The University of California		<input type="checkbox"/>
19	WO 98/22168	WO		1998-05-28	Liebel-Flarsheim Company		<input type="checkbox"/>

If you wish to add additional Foreign Patent Document citation information please click the Add button

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T ⁵
	1	HORAK et al., "Hydrogels in endovascular embolization. III. Radiopaque spherical particles, their preparation and properties: Biomaterials, GB, Elsevier Sciences Publishers BV., Barking, Vol. 8, 03/01/1987, pgs. 142-145	<input type="checkbox"/>
	2	HODDE, J.P. et al., "Glycosaminoglycan Content of Small Intestinal Submucosa: A Bioscaffold for Tissue Replacement," Tissue Engineering, Vol. 2, No. 3, 1996, pp. 209-217, XP002063373	<input type="checkbox"/>
	3	Guideline on Validation of the Limulus Amebocyte Lysate Test as an End-Product Endotoxin Test for Human and Animal Parenteral Drugs, Biological Products, and Medical Devices," Dec. 1987, Ctr for Drug Evaluation & Research, Ctr for Biologic Evaluation & Research, Ctr for Devices & Radiological Health and Ctr for Veterinary Medicine	<input type="checkbox"/>
	4	American National Standard, ANSI/AAMI 10993-1:1994, "Biological Evaluation of Medical Devices - Part 1: Guidance on Selection of Tests," Association for the Advancement of Medical Instrumentation, pp. 9-17	<input type="checkbox"/>

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	10044031
Filing Date	2002-01-11
First Named Inventor	Badylak et al.
Art Unit	3774
Examiner Name	Paul B. Prebilio
Attorney Docket Number	3220-69262

5	BLOCK, S., "Peroxygen Compounds," Disinfection, Sterilization and Preservation, 5th Edition 2001, pp. 185-204, Lippincott Williams & Wilkins, Philadelphia, PA	<input type="checkbox"/>
6	CLARKE, K.M. et al., "Intestine Submucosa and Polypropylene Mesh for Abdominal Wall Repair in Dogs," The Journal of Surgical Research, Jan. 1996, Vol. 60, No. 1, pp. 107-114	<input type="checkbox"/>
7	DENTON, G.W., "Chlorhexidine," Disinfection, Sterilization and Preservation, S. Block, editor, 5th Edition, 2001, pp. 321-336, Lippincott Williams & Wilkins, Philadelphia, PA	<input type="checkbox"/>
8	Hawley's Condensed Chemical Dictionary, Eleventh Edition, Van Nostrand Reinhold Company, 1987, pps. 886 and 890	<input type="checkbox"/>
9	KROPP, B.P. et al., "Regenerative Urinary Bladder Augmentation Using Small Intestinal Submucosa: Urodynamic and Histopathologic Assessment in Long-Term Canine Bladder Augmentations," The Journal of Urology, June 1996, Vol. 155, No. 6, pp. 2098-2104	<input type="checkbox"/>
10	KROPP, B.P. et al., "Experimental Assessment of Small Intestinal Submucosa as a Bladder Wall Substitute," Urology, Sept. 1995, Vol. 46, No. 3, pp. 396-400	<input type="checkbox"/>
11	PREVEL, C.D. et al., "Small Intestinal Submucosa: Utilization as a Wound Dressing in Full-Thickness Rodent Wounds," Annals of Plastic Surgery, Oct. 1995, Vol. 35, No. 4, pp. 381-388	<input type="checkbox"/>
12	PREVEL, C.D. et al., "Small Intestinal Submucosa: Utilization for Repair of Rodent Abdominal Wall Defects," Annals of Plastic Surgery, Oct. 1995, Vol. 35, No. 4, pp. 374-380	<input type="checkbox"/>
13	Wikipedia online definition for "collagen"	<input type="checkbox"/>
14	European Search Report, Patent Application No. 08012454.8	<input type="checkbox"/>
15	"Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing," FDA Blue Book Memorandum No. G95-1	<input type="checkbox"/>

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	10044031
Filing Date	2002-01-11
First Named Inventor	Badylak et al.
Art Unit	3774
Examiner Name	Paul B. Prebilio
Attorney Docket Number	3220-69262

16	PROBST, M. et al., "Reproduction of functional smooth muscle tissue and partial bladder replacement," British J. of Urology, 1997; 79:505-515	<input type="checkbox"/>
17	SUTHERLAND, R.S. et al., "Regeneration of bladder urothelium, smooth muscle, blood vessels and nerves into an acellular tissue matrix," J. of Urology, 1996; 156:571-577	<input type="checkbox"/>
18	European Search Report EP 08008810, June 27, 2008	<input type="checkbox"/>
19	International Search Report, WO 00/32250	<input type="checkbox"/>
20	International Search Report, WO 00/32253	<input type="checkbox"/>
21	U.S. Patent Application Serial No. 12/693,908	<input type="checkbox"/>
22	U.S. Patent Application Serial No. 12/695,225	<input type="checkbox"/>

If you wish to add additional non-patent literature document citation information please click the Add button

EXAMINER SIGNATURE

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.